

FEB 24 2000

K000572

510(k) SUMMARY
[21 CFR 807.92]

February 24, 2000

Submitted by: Tri-Ject International Corporation
310 Meridian N., Suite 6
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Establishment Registration Number 9038098

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Contract: Peter G. Lemin, President/CEO

Device Description: The device consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a luer connector fitting for attaching a hypodermic single lumen needle. The barrel contains a retractable mechanism that becomes engaged after injection of the contents. Withdrawal of the plunger then holds the needle securely inside the syringe barrel.

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
[21 CFR 807.92]

510(k) Number:	K000572
Proprietary Name:	ENSI™ Syringe
Common Name:	Retracting Needle Syringe
Classification Name:	Piston Syringe (21CFR 880.5860)
Manufacturer:	Uni-Ject Australia PTY LTD 19-21 Peninsula Boulevard Seaford, Victoria 3198 Australia
Predicate Device Information:	A claim of substantial equivalence is made to: USMI SafeSnap™ Syringe, K925039 BD syringe (pre-Amendment device)
Device Claims:	For the injection of fluids into the body, while helping to reduce the risk of sharps injuries.

In compliance with the requirements of the Safe Medical Device Act (SMDA) of 1990, the following information is submitted as a summary of safety and effectiveness information for this 510(k) premarket notification.

Effectiveness

In a simulated use study conducted at two (2) hospitals and a large medical center, more than 100 investigators tested 580 ENSI™ syringes to evaluate the effectiveness of the product in injecting fluids into a patient. All injections were successfully completed and 100% of the investigators had a positive response to the syringe evaluation.

Bench testing of the product confirms its compliance with the applicable performance standards established by the International Standards Organization (ISO).

Safety

In a simulated use study by a variety of doctors (MD's), Registered Nurses (RN's), and Emergency Medical Technicians (EMT's), over 580 ENSI™ syringes were tested to evaluate the safety of the product in injecting fluids into a patient. No injuries of any kind were reported.

Bench testing of the product confirms its comparability with legally-marketed predicate devices for a variety of safety factors, including but not limited to graduation accuracy.

Biocompatibility testing was performed by outside contract laboratories, with the results indicating that, from a biocompatibility standpoint, the product is safe for its intended purpose.

A variety of design factors are intended to improve upon patient and clinician safety during use of the product. While sample size requirements have precluded a broad statistical study of the impact of such factors on injury rates, 100% of the clinicians that actually tested the product expressed overall satisfaction with it.

A detailed risk analysis was performed on the product and, based on information currently available, the risk of harm from the product appears to be relatively low.

Sterilization validation was conducted by an outside contract laboratory. Sterilization to a SAL of 10^{-6} was confirmed during the tests. Pyrogenicity was also evaluated and acceptable results obtained.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2000

Mr. Peter G. Lemin
President/CEO
Tri-Ject International Corporation
310 Meridian N., Suite 6
Puyallup, Washington 98371

Re: K000572
Trade Name: ENSI™ Syringe
Regulatory Class: II
Product Code: MEG
Dated: February 17, 2000
Received: February 22, 2000

Dear Mr. Lemin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

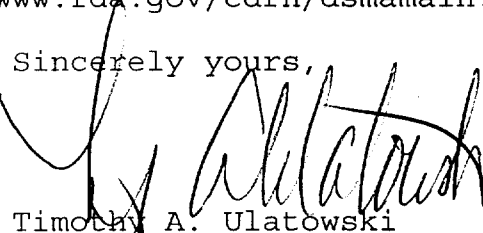
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000572

February 23, 2000

INDICATION FOR USE

The ENSI™ Syringe is a sterile, single use, disposable syringe for injecting fluids into the body, while helping to reduce the risk of sharps injuries.

A handwritten signature in black ink, appearing to read "L. A. [unclear]", written over a horizontal line.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number 000572

Prescription
use only